



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appeal Brief Transmittal Form
ZEN 017

AF/IFW

In re Application of: O'Lenick

Examiner: Meller, Michael V.

Group Art Unit: 1655

Serial No: 10/620,899

Filed: 07/17/2003

Title: Cranberry Alkoxy Esters as a Delivery System for Natural Antioxidants

Please find attached

1. Appeal Brief
2. Fee For Filing Appeal Brief \$250.00

Applicant is a small entity.

Respectfully submitted

Anthony J. O'Lenick
Pro-Se Inventor
Appellant
2170 Luke Edwads Road
Dacula, Ga 30019
July 29, 2006



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(A) Identification page

In re Application of: LaVay

Examiner: Meller, Michael V.

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(C) Real party in interest page;

The real party in interest in the Appeal are Carter LaVay and Anthony J. O'Lenick, Jr., pro-se inventors.

(D) Related appeals and interferences page(s);

There are four appeals that relate to exactly the same issue. They are:

1) ZEN-012

In re Application of: O'Lenick **Examiner:** Meller, Michael V.

Group Art Unit: 1655 **Serial No:** 10/444,471

Filed: 05/27/2003

Title: Guerbet Raspberry Esters as a Delivery System for Natural Antioxidants

2) ZEN-013

In re Application of: O'Lenick **Examiner:** Meller, Michael V.

Group Art Unit: 1655 **Serial No:** 10/444,470

Filed: 05/27/2003

Title: Guerbet Cranberry Esters as a Delivery System for Natural Antioxidants

3) ZEN 15

In re Application of: O'Lenick

Examiner: Meller, Michael V.

Group Art Unit: 1655

Serial No: 10/600,251

Filed: 06/23/2003

Title: Cranberry Amido Amines and Betaines as a Delivery System for Natural Antioxidants

4) ZEN 017

In re Application of: O'Lenick

Examiner: Meller, Michael V.

Group Art Unit: 1655

Serial No: 10/620,899

Filed: 07/17/2003

Title: Cranberry Alkoxy Esters as a Delivery System for Natural Antioxidants

(E) Status of claims page;

Claims 1-9 are rejected and Claims 10-19 are withdrawn. Despite the fact that only claims 1-9 are currently pending and claims 10-19 are withdrawn, applicant respectfully points out that claims 1-9 are directed toward a compound, and claims 10-19 are directed toward the use of the novel compound. Applicant respectfully requests that the policy established by USPTO relating to rejoining claims directed to a process for using compounds be rejoined once the compound claims have been allowed.

(F) Status of amendments page

All Amendments have been entered including one filed on July 2, 2006 marked Amendment after Final Rejection.

(G) Summary of claimed subject matter page(s);

The following is taken directly from the application:

[002] The present invention relates to cranberry seed oil derivatives derived by the reaction of polyoxyalkylene glycol and cold pressed cranberry seed oil. The choice of cold pressed cranberry seed oil as a raw material in the preparation of the compounds of the present invention is critical, since it has been found that the cold pressed cranberry seed oil contains a unique antioxidant which when reacted with polyoxyalkylene glycol resulting in products that deliver said actives to the skin and hair, resulting in protection of the skin and hair from environmental factors such as acid rain, ozone attack and UV degradation.

[003] U.S. patent 6,391,345 issued May 2002 describes the refining of cold pressed cranberry seed oil, and is incorporated herein by reference. American cranberries, *Vaccinium macrocarpon*, are native plants of open, acid peat bogs in North America. Cranberry plants are evergreen perennial vines that produce runners and upright branches with terminal flower buds.

[004] Cranberries have historically been harvested and either ingested as whole berries, such as in cranberry sauce, or have been processed for their juice. Pulp remaining after cranberry juice extraction processing has historically been regarded as an undesirable waste product with little or no utility.

[005] In the United States, cranberries are grown and are harvested in the Northeast, Northwest and Great Lakes regions. Cranberries ripen and are harvested in autumn, which has made cranberries a holiday food. Cranberries have not changed significantly in appearance and nutritional value over

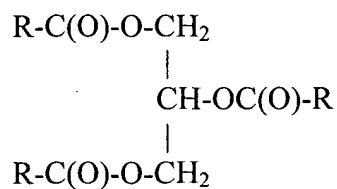
time. Cranberries have typically been stored by freezing or drying the whole berries.

[006] Cranberries have become a popular food only in recent years because cranberries have a very bitter taste. Historically, processors have not dealt well with the taste. Cranberries are known to contain quinic acid. It is the quinic acid that imparts to cranberries, the bitter taste. Cranberry juice has become more palatable because it is blended with other sugar-containing aqueous liquids.

[007] Apart from an undesirable taste, quinic acid is believed to have nutraceutical properties.

When ingested, quinic acid is converted to hippuric acid. Hippuric acid is believed to remove toxins from the bladder, kidneys, prostate and testicles. Under normal circumstances, oils useful in the cosmetic industry are refined with a variety of steps that are designed to maximize triglyceride content, and minimize color and odor. These steps include steam distillation, a process in which steam is sparged through the oil to remove odor and color bodies and solvent extraction with compounds like hexane, which remove additional odor and color bodies. We have learned that these processes, while improving color and odor, remove many of the desirable “active” materials like tocopherols, antioxidants and the like. What results is a light color, low odor triglyceride with no appreciable added skin benefits. We have surprisingly learned that when the cranberry seed oil that is cold processed is reacted with specific compounds, the actives (normally removed in non-cold press process) remain in the product, become water-soluble and have outstanding activity on the skin. In essence two things happen when the cold pressed cranberry seed oil is reacted with polyoxyalkylene glycols. First the triglyceride reacts giving a product which is water-soluble. Secondly, the water-soluble product solubilized the active components there as a consequence of cold pressing. Thirdly, these very desirable materials are deposited on the skin and have a proclivity to remain on the skin. The result is a unique delivery of the actives to the skin from totally natural fruit oil.

[015] Cold Pressed Cranberry Oil is a triglyceride conforming to the following structure:



[016] The R-C(O)- group has the following composition:

| <u>Component</u> | <u>% Weight</u> |
|---------------------------|-----------------|
| 16:0 palmitic | 5.0 to 6.0 |
| 18:0 stearic | 1.0 to 2.0 |
| 18:1 oleic | 20 to 25 |
| 18:2 linoleic | 35 to 40 |
| 18:3 linolenic (alpha) | 30 to 35 |
| 20:0 arachidic | 0.13 |
| 20:1 gadoleic | 0.20 |
| 20:5 (n-3) | 0.32 |
| 22:2 | 1.1 |
| Myristic | 0.01 |
| Pentadecanoic | 0.02 |
| Palmitoleic (trans) | 0.13 |
| Palmitoleic (cis) | 0.08 |
| 10-heptadecanoic | 0.03 |
| Gamma linolenic | 0.1 to 0.2 |
| Nonadecanoic | 0.1 to 0.2 |
| 11-transeicosenic | 0.22 |
| 11, 14 eicosandienoic | 0.1 |
| 11, 14, 17 eicosatrienoic | 0.01 |
| Eicosapentaenoic | 0.01 |
| Behenic | 0.03 |
| Erucic | 0.02 |
| Docosapentaenoic | 0.01 |
| Tricosanoic | 0.01 |
| Lignoceric | 0.02 |

[017] The oil also contains the following very critical “active” components for skin and hair care:

| <u>Compound</u> | <u>mg/kg</u> |
|------------------------------------|--------------|
| Campesterol/brassicasterol (mg/kg) | 66.0 |
| Stigmasterol (mg/kg) | 68.0 |
| Beta-sitosterol (mg/kg) | 1319.0 |
| Phosphatidylinositol (mg/kg) | 9.9 |
| Phosphatidylcholine (mg/kg) | 202.0 |
| Alpha-tocopherol (mg/kg) | 341.0 |
| Gamma-tocopherol (mg/kg) | 110.0 |

[018] When the oil is exposed to steam strip and solvent extraction the concentration of the “active” components drops to vanishingly small levels and the activity is lost.

[019] As can be seen, the cold pressed cranberry seed oil is a rich source of compounds having important properties when applied to hair and skin. Stigmasterol is an anti-stiffness factor. Beta-sitosterol has use as an antihyperlipoproteinemic agent. One or more of the campesterol, stigmasterol and beta-sitosterol has inflammatory activity and may be useful in the treatment of gingivitis, rash, eczema, and other skin lesions. It is also believed that these compounds found in cranberry seed oil have activity as sunscreen agents. Since some of the compounds present in cranberry oil have absorbance in the UV-B range. It is this range that causes the greatest cellular damage. The cold pressed cranberry oil can shield against UV-A induced damage by scattering light as well as by light spectrum absorption. The cold pressed cranberry oil has, then activity as a broad spectrum UV protectant. The cranberry oil may be used alone or in combination with other conventional sunscreens.

[020] The phosphatidylinositol and phosphatidylcholine and tocopherols are highly desirable materials used on skin. The phosphatidylcholine, also known as lecithin, is found in human beings in the nervous system and the brain. Lecithin also has use as an edible and digestible surfactant. It is usable in manufacturing foods such as margarine and chocolate. Lecithin is a natural antioxidant that can increase oil stability and shelf life. Lecithin also has use in pharmaceuticals, cosmetics,

skin care, and in treating leather and textiles.

[021] Cold pressed cranberry seed oil has a very high concentration of gamma tocopherol. This level is much higher than is found in oils such as safflower and grape, which are 11 and 33, respectively. The gamma tocopherol has the most antioxidant capacity of all of the tocopherols and contributes to the stability of highly unsaturated oils in the cranberry oil. It is believed that the presence of the high gamma tocopherol concentration makes cranberry oil an excellent additive to animal food-both human and non-human. The gamma tocopherol may be as important as alpha tocopherol in preventing degenerative diseases.

[022] Cold pressed cranberry seed oil has a high linolenic acid content. Linolenic acid has been implicated as a food additive and nutraceutical in preventing coronary heart disease and cancer. Cranberry oil also has a high polyunsaturated: saturated ratio in a neutral lipid fraction, of 10:1. This ratio is regarded as having value in reducing serum cholesterol, atherosclerosis and in preventing heart disease.

[023] Cold pressed cranberry seed oil has a rather dark yellow to orange color because it contains carotenoids. The carotenoids are usable as colorant substitutes for materials such as carotenes, annotos, and apocarotenals used in the nutraceutical and oil industries.

R is derived from cold pressed cranberry seed oil and has the following composition:

| <u>Component</u> | <u>% by Weight of "R"</u> |
|------------------------|---------------------------|
| 16:0 palmitic | 5.0 to 6.0 |
| 18:0 stearic | 1.0 to 2.0 |
| 18:1 oleic | 20 to 25 |
| 18:2 linoleic | 35 to 40 |
| 18:3 linolenic (alpha) | 30 to 35 |
| 20:0 arachidic | 0.13 |
| 20:1 gadoleic | 0.20 |
| 20:5 (n-3) | 0.32 |
| 22:2 | 1.1 |
| Myristic | 0.01 |
| Pentadecanoic | 0.02 |

| | |
|---------------------------|------------|
| Palmitoleic (trans) | 0.13 |
| Palmitoleic (cis) | 0.08 |
| 10-heptadecanoic | 0.03 |
| Gamma linolenic | 0.1 to 0.2 |
| Nonadecanoic | 0.1 to 0.2 |
| 11-transeicosenic | 0.22 |
| 11, 14 eicosandienoic | 0.1 |
| 11, 14, 17 eicosatrienoic | 0.01 |
| Eicosapentaenoic | 0.01 |
| Behenic | 0.03 |
| Erucic | 0.02 |
| Docosapentaenoic | 0.01 |
| Tricosanoic | 0.01 |
| Lignoceric | 0.02 |
| Nervonic | 0.02 |

[030] Also present in the product are the following “actives”

Compound

Campesterol/brassicasterol

Stigmasterol

Beta-sitostero

Phosphatidylinositol

Phosphatidylcholine

Alpha-tocopherol

Gamma-tocopherol

[043] COLD PRESSED CRANBERRY SEED OIL

[044] Cold Presses Cranberry seed oil is an item of commerce sold by Regal Trade & Consult

LLC. of Hoboken, N.J. It is processed using U.S. patent 6,391,345 issued May 2002, only applied to Cranberry seed oil not cranberry seed oil.

(H) Grounds of rejection to be reviewed on appeal page(s);

1. The only rejection and issue at hand is a rejection under 35 USC 112, first paragraph as failing to comply with the written description. The office action dated June 27, 2006 states “ There is no chemical structure for ”R” and since that is the case is it not clear what “R” is. It is defined as derived from cold pressed Cranberry, but without a chemical structure of it, it is not adequately defined by the instant specification”. This statement clearly defines the appeal. It is important to note during prosecution and one claim (number 4) was allowed, and then rejected.

2. Clearly, the issue is if the only acceptable method of naming the natural oil from which the compounds of the present invention are derived is with words like ““R” is alkyl having x to y carbon atoms”. Applicant rejects the contention. The Federal Circuit has clearly articulated the position that definiteness must be analyzed in light of (1) the content of a particular application disclosure, (2) teachings of the prior art, (3) claim interpretation that would be given by one possessing the ordinary level of skill in the art.

(Ref: In Re Marosi, 710 F.2d 218, U.S.P.Q. 289 (Fed Cir 1983); Rosemount Inc. v. Beckman Instruments Inc. 727 F.2d 1540, 221 U.S.P.Q. 1 (Fed Cir 1984).

The term “R is derived from cold pressed cranberry seed oil” as written complies fully with the requirements of 35 USC 112 (first paragraph). There is nothing of record to indicate to the contrary except opinion. The application painstakingly specifies the oil, the genus and species from which it is derived, a patent enabling the term cold pressed, and the information that is known about the composition. ([013] to [019] of the application, and buttressed the argument with an affidavit under 37 CFR 1.132.

3. Applicant respectfully contends that the language saying R is derived from cold pressed cranberry seed oil has proper antecedent basis and complies with 35 USC 112. The alkyl chain and the other listed elements are present in cold pressed cranberry oil. Applicant respectfully contends

that the patent literature is replete with many examples of natural products claimed using a specific oil. The specific way the applicant has defined the oil not only complies with 35 USC 112 but to deny the claims would deny the applicant the present invention. The claims not only enable one of ordinary skill in the art to practice the current invention, the invention as claimed defined cold pressed oil in the most particular way possible.

4. Applicant respectfully contends and has submitted an expert declaration stating that that natural products like polymers are complex mixtures of species made up described by the inventor in great detail in the specification and confirmed in the Steinberg Declaration. Applicant points out that by describing the “R” group as requested by the current office action with a certain alkyl chain length would not work since the product so described could be made by blending oils or fatty acids that are not the specified cold pressed oil and would not be functional. Such a description would not define the present invention in full, clear and concise and exact terms as to enable any person skilled in the art to which it pertains ... to carry out the invention. The natural oils that are described as “derived from cold pressed oil” tell the genus and species of the plant from which they are derived, the method of processing the oil, and the antioxidant materials present. It is the only way to describe the product the inventor claims as his invention.

5. There is nothing of record to specify why the language used in non-enabling, or why the allowed claim in the Quayle action was withdrawn. Further applicant respectfully contends that the pertinent portion of 112 is second paragraph not first which states;

¶ 7.34.01 Rejection, 35 U.S.C. 112, 2nd Paragraph, Failure To Particularly Point out and Distinctly Claim (Indefinite)

Claim [1] rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Examiner Note:

1. This rejection must be preceded by form paragraph 7.30.02 or 7.103.2. This form paragraph should be followed by one or more of the following form paragraphs 7.34.02 - 7.34.11, as applicable. If none of these form paragraphs are appropriate, a full explanation of the deficiency of the claims should be supplied. Whenever possible, identify the particular term(s) or limitation(s) which render the claim(s) indefinite and state why such term or limitation renders the claim indefinite. If the scope of the claimed subject matter can be determined by one having ordinary skill in the art, a rejection using this form paragraph would not be appropriate. (Emphasis added)

(I) Argument page(s);

A. Rejection is Vague, Indefinite and Unsupported by the Record

While never specifically elucidated in any of the office actions, the only issue in the current appeal is does the term “R is derived from cold pressed raspberry seed oil;” is satisfactory in light of the antecedent basis provided in the specification. The contention there is no definition of “R” is simply unsupportable. Appellant has repeatedly asked for clarification even in the form of a Pre-appeal Brief, but has gotten no relief. If the contention is there is no “R” definition, appellant traverses the contention. A simple reading of the claim and the prior ex-parte Quayle action affirms this.

B. Rejection is inconsistent with USPTO Practices

Appellant is also quite perplexed with the rejection that the term “is derived from” is rejectable under 35 USC 112. A claim search on the USPTO site shows some 78,088 such claims in allowed U.S. Patents.

**Results of Search in US Patent Collection db for:
ACLM/"is derived from": 78088 patents.
*Hits 1 through 50 out of 78088***

While appellant understands the granting of a specific patent does not render the practice correct, the sheer number of these claims and the desire of the USPTO to have some uniformity in how they handle claim language speaks to allowance. There is no specific reference to why the language has been determined to be inadequate, despite several requests for such data.

C. Rejection is inconsistent with MPEP Requirements

Much has been made of the fact that the appellant is a *pro se* inventor. Appellant points to two sections of the MPEP which should apply to this case since an ex-parte Quayle allowance was given the withdrawal of which was never explained despite several requests.

707.07(j) State When Claims Are Allowable [R-2]

>

I. < INVENTOR FILED APPLICATIONS

When, during the examination of a *pro se* application it becomes apparent to the examiner that there is patentable subject matter disclosed in the application, the examiner should draft one or more claims for the applicant and indicate in his or her action that such claims would be allowed if incorporated in the application by amendment.

This practice will expedite prosecution and offer a service to individual inventors not represented by a registered patent attorney or agent. Although this practice may be desirable and is permissible in any case deemed appropriate by the examiner, it will be expected to be applied in all cases where it is apparent that the applicant is unfamiliar with the proper preparation and prosecution of patent applications.

II. < ALLOWABLE EXCEPT AS TO FORM

When an application discloses patentable subject matter and it is apparent from the claims and applicant's arguments that the claims are intended to be directed to such patentable subject matter, but the claims in their present form cannot be allowed because of defects in form or omission of a limitation, the examiner should not stop with a bare objection or rejection of the claims. The examiner's action should be constructive in nature and, when possible, should offer a definite suggestion for correction. Further, an examiner's suggestion of allowable subject matter may justify indicating the possible desirability of an interview to accelerate early agreement on allowable claims.

D. Rejection is inconsistent Case Law

Applicant respectfully contends that he has fulfilled all requirements under 35 USC 112 and the rejection should be withdrawn. In order for the rejection to be properly made, it must comply with the MPEP requirements and the requirements of law and precedent.

D.1. The present rejection fails to establish a proper rejection under 35 USC 112.

35 U.S.C. § 112, paragraphs 1 and 2 read as follows:

The specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

In re Moore, 439 F.2d 1232, 169 U.S.P.Q. 236 (C.C.P.A. 1971), is considered a time-honored, basic articulation of the analysis in evaluating compliance with the various requirements of 35 U.S.C. § 112. According to Moore, an analysis should begin with the determination of whether the claims satisfy the requirements of the second paragraph. Recognizing the "awkwardness" of treating the first and second paragraphs in inverse order, the CCPA explained:

[I]t should be realized that when the first paragraph speaks of "the invention", it can only be referring to that invention which the applicant wishes to have protected by the

patent grant, *i.e.*, the *claimed* invention. For this reason, the claims must be analyzed first in order to determine exactly what subject matter they encompass.

A seminal case on the construction of the second paragraph of section 112 is *In re Borkowski*, 422 F.2d 904, 164 U.S.P.Q. 642 (C.C.P.A. 1970), where the CCPA observed:

The first sentence of the second paragraph of § 112 is essentially a requirement for *precision and definiteness* of claim language. If the scope of subject matter embraced by a claim is clear, and if the applicant has not otherwise indicated that he intends that claim to be of a different scope, then the claim does particularly point out and distinctly claim the subject matter which the applicant regards as his invention.

Id. at 909, 164 U.S.P.Q. at 645-46 (footnote omitted).

It is clear from the above-cited language of Borkowski, that the second paragraph of section 112 that the requirement calls for precision and definiteness. In other words, one skilled in the art must be able to tell with a reasonable degree of certainty whether his or her conduct is within or outside the scope of the claim. Simply stated, the claims must not be "vague or indefinite" and must clearly set out the boundaries of the subject matter for which protection is granted by the patent.

Consequently, a claim that is understandable to one skilled in the art and that defines subject matter that applicant regards as the invention meets the requirements of 35 U.S.C. § 112, second paragraph. Stated another way, all that is required by the second paragraph of section 112 is that the claims set out and circumscribe a particular area that the applicant regards as the invention with a reasonable degree of precision and particularity.

The Federal Circuit has had the opportunity to decide a number of section 112, second paragraph issues. It is clear from these cases that definiteness of claim language must be analyzed, not in a vacuum, but in light of (1) the content of the particular application disclosure, (2) the teachings of the prior art, and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. See, for example,

In re Marosi, 710 F.2d 799, 218 U.S.P.Q. 289 (Fed. Cir. 1983); Rosemount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, 221 U.S.P.Q. 1 (Fed. Cir. 1984); W.L Gore & Assocs., Inc. v. Gartock, Inc., 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983).

**E. The present rejection fails to properly take into consideration the
Expert Declaration of Record.**

It is quite interesting that the only expert information is the declaration of David Steinberg already of record and attached hereto. He clearly states: In conclusion, in my expert opinion, the Applicant language saying R is derived from cold pressed oil has proper antecedent basis and is abundantly clear to one of ordinary skill in the art. (emphasis added). This declaration was held unpersuasive for no apparent reason of record.

This despite the fact that it has long been held that determining whether the written description requirement is satisfied requires reading the disclosure in light of the knowledge possessed by those skilled in the art. That knowledge can be established by affidavits of fact composed by experts, and by reference to patents and publications available to the public prior to the filing date of the application. See, e.g., In re Alton, 76 F.3d 1168, 37 U.S.P.Q.2d 1578 (Fed. Cir. 1996); In re Lange, 644 F.2d 856, 209 U.S.P.Q. 288 (C.C.P.A. 1981).

In re Alton involved an appeal of a PTO Board of Appeals decision that the specification did not provide adequate written descriptive support for the claimed invention. The subject matter of the patent application was directed to an amino acid sequence of human gamma interferon (IFN), a protein secreted by cells in the immune system to stimulate immunological activity. 76 F.3d at 1170, 37 U.S.P.Q.2d at 1579.

The board reversed the examiner's rejections but denied patentability under section 112, first paragraph, holding that the specification failed to describe adequately the subject matter of the claims. Specifically, the board found that "[t]he closest analog to that claimed herein is described [in Example 5]. This particular analog, though similar to that claimed herein, does not constitute a description of the claimed analog." *Id.* at 1171, 37 U.S.P.Q.2d at 1580. Alton opted for further prosecution under 37 C.F.R. 1.196(b) (1994) and submitted a declaration by Dr. Randolph Wall. The examiner issued a final rejection based on section 112, first paragraph and dismissed the Wall declaration as opinion evidence, stating "[L]ittle weight is given an opinion affidavit on the ultimate legal question at issue." *Id.* The board affirmed the section 112, first paragraph rejection, holding that "the specific polypeptide of claim 70 was not described in the original specification," and adopted the examiner's dismissal of the Wall declaration.

The Federal Circuit held that the final rejection contained two errors: first, viewing the Wall declaration as addressing an issue of law instead of an issue of fact; second, failing to articulate adequate support for the § 112, first paragraph rejection. See *id.* at 1174, 37U.S.P.Q.2dat1583.

With respect to the first error, the Federal Circuit stated:

It is well settled that the question of whether a specification provides an adequate written description of the subject matter of the claims is an issue of fact. Therefore, the examiner was in error when he stated that the Wall declaration, which attempted to shed light on whether the '451 specification adequately described the subject matter of claim 70, addressed a legal issue. *Id.* at 1174, 37 U.S.P.Q.2d at 1583.

The Federal Circuit held that the Wall declaration did not assert an opinion on the patentability of the claimed analog but rather offered factual evidence in an attempt to explain why one of ordinary skill in the art would have understood the specification as describing the claimed

invention. See *id.* at 1174-75, 37 U.S.P.Q.2d at 1583. Furthermore, the Federal Circuit stated that the use of the words "it is my opinion" to preface what someone of ordinary skill in the art would have known does not transform the factual statements contained in a declaration into opinion testimony. *Id.* at 1175, 37U.S.P.Q.2dat1583.

With respect to the second error, the Federal Circuit noted that the examiner bears the initial burden of presenting a *prima facie* case of unpatentability. That burden may be met with evidence that one skilled in the art would fail to "recognize in the disclosure a description of the invention defined by the claims." See *id.* at 1175, 37 U.S.P.Q.2d at 1583, (quoting *In re Wertheim*, 541 F.2d 257, 263, 191 U.S.P.Q. 90,97 (C.C.P.A. 1976)). Once that burden is met, the applicant must provide evidence that the invention is adequately described to one skilled in the art. See *id.* In this case, the Wall declaration was submitted to rebut the section 112, first paragraph rejection.

The examiner did not respond to the main thrust of the Wall declaration. Therefore, the Federal Circuit held that the examiner incorrectly dismissed the declaration without sufficiently explaining why a person skilled in the art would not recognize that the inventor had possession of the claimed subject matter at the time the application was filed. See *id.* at 1176, 37 U.S.P.Q.2d at 1584.

E. The Rejection deprives the Applicant of what they Regards as the Invention

The applicant chose the language carefully, thoughtfully and intentionally to comply with the Best Mode Requirement. In fact the only declaration of record states it is the only way to properly claim the invention. Such a assertion is amatter of fact and cannot be a simple matter of opinion.

“[T]he disclosure in question must be read in light of the knowledge possessed by those skilled in the art, and that knowledge can be established by affidavits of fact composed by an expert, and by reference to patents and publications available to the public prior to appellant's filing date.

Id. at 863, 209 U.S.P.Q. at 294

Lange submitted an affidavit by an expert that indicated that a construction of the term "element" in the grandparent application as referring to chemically elemental fluorine would be inconsistent with basic chemical principles, since fluorine would not be stable in the elemental state on or within the electrodes described in detail in the grandparent application. Instead, the fluorine would react with adjacent materials to form compounds. As evidenced by a reference of record, the affidavit further indicated that compounds capable of generating the electronegative gases "would be readily apparent to one skilled in the art." Id. at 864, 209 U.S.P.Q. at 294.

Relying on the affidavit submitted by Lange, as well as the references of record that were cited to indicate the level of ordinary skill in the art at the time appellant's grandparent application was filed, the court concluded that one skilled in the art "would substitute the broader terms, substances or compounds, for elements when reading the grandparent's specification."

If the provincial interpretation that it is improper to the use of the term "is derived from" is accepted by the board, it will virtually eliminate the possibility of properly claiming products based upon natural raw materials or polymers, since these raw materials contain numerous components for which full structure elucidation has yet to be developed. It has long been established that patents should not be limited by lack of availability of analytical methods.

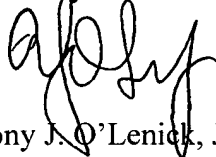
It is critical to note that it is not the alkyl chain as required in the rejection that enables the invention, but the selection of the proper oil with all its components. Appellant has made it

abundantly clear the CAS number of the oil, the genus and species of the oil, the composition of the oil as currently known and the patent reference to the process of refining the oil (incorporated by reference). Claiming simply by alkyl chain, while satisfying the rejection, could well read on blended compositions not derived from the specified oil. Claiming the product this way would not comply with the pro se inventor's duty of candor.

Appellant respectfully contends that the standard to be applied under 35 USC 112 is if in fact one of ordinary skill in the art would know what is within the scope of the claimed invention. The office actions in this file are not clear as to why it is felt there is a rejection under 35 USC 112, nor is there any recommendation as to how to correct the perceived deficiency. The only information of record and the only information to be considered in this appeal is the expert declaration, ignored in prosecution, which clearly states that one of ordinary skill in the art would know if they infringe. There is virtually nothing of record to explain the logic or basis of the rejection, nor what caused it to be imposed after an ex-parte Quayle allowance.

Appellant respectfully requests the Board to rule that the claims now pending one of which was originally allowed be allowed and the rejection be overturned.

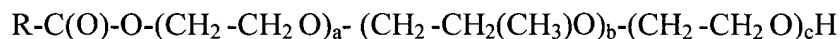
Respectfully submitted



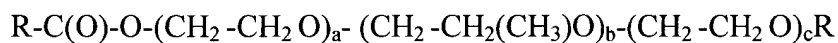
Anthony J. O'Lenick, Jr.
Pro-Se Inventor
2170 Luke Edwards Road
Dacula, Ga 30019
July 29, 2006

(J) Claims appendix page;

1. A cranberry polyoxyalkylene glycol ester composition conforming to the following structure:



and



wherein;

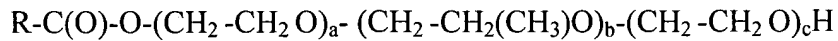
R is derived from cold pressed cranberry;

a, b and c are independently integers ranging from 0 to 40, with the proviso that $a + b + c$

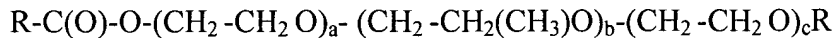
equal at least 5.

2. A composition of claim 1 wherein a is 5, b is 0, and c is 0.
3. A composition of claim 1 wherein a is 5, b is 5, and c is 5.
4. A composition of claim 1 wherein a is 0, b is 10, and c is 0.
5. A composition of claim 1 wherein a is 10, b is 10, and c is 0.
6. A composition of claim 1 wherein a is 20, b is 5, and c is 20.
7. A composition of claim 1 wherein a is 1, b is 10, and c is 5.
8. A composition of claim 1 wherein a is 40, b is 40, and c is 40.
9. A composition of claim 1 wherein a is 10, b is 10, and c is 15.

10. A process for treating hair and skin with an effective antioxidant concentration of a cranberry polyoxyalkylene glycol ester composition conforming to the following structure:



and



wherein;

R is derived from cold pressed cranberry;

a, b and c are independently integers ranging from 0 to 40, with the proviso that $a + b + c$

equal at least 5.

11. A process of claim 10, wherein said effective antioxidant concentration ranges from

0.1% to 10.0% by weight.

12. A process of claim 11 wherein a is 5, b is 0, and c is 0.

13. A process of claim 11 wherein a is 5, b is 5, and c is 5.

14. A process of claim 11 wherein a is 0, b is 10, and c is 0.

15. A process of claim 11 wherein a is 10, b is 10, and c is 0.

16. A process of claim 11 wherein a is 20, b is 5, and c is 20.

17. A process of claim 11 wherein a is 1, b is 10, and c is 5.

18. A composition of claim 11 wherein a is 40, b is 40, and c is 40.

19. A process of claim 11 wherein a is 10, b is 10, and c is 15.

(K) Evidence appendix page(s);

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

DECLARATION UNDER 37 CFR 1.132

David C. Steinberg declares as follows:

1. I am currently President of Steinberg & Associates, Inc. a consulting corporation I founded. I have also been Vice President of Research at Hansotech, a company in the wax, oils and fats business. I also was employed at Emery Industries (now Cognis) a key manufacturer of fatty products.
2. I am considered an expert in the fields of oils, waxes and butters and consult regularly in the field to many corporations. I have also been an expert witness in the field. I have over 30 years experience in this field.
3. I am certainly one of ordinary skill in the art of products derived from natural oils.
4. I have reviewed four related applications currently pending before the United States Patent Office. These applications are:

Serial No: Filed

10/444,470 05/27/2003

**Title: Guerbet Cranberry Esters as a Delivery System for
Natural Antioxidants**

Serial No: Filed:

10/444,471 05/27/2003

**Title: Guerbet Raspberry Esters as a Delivery System for
Natural Antioxidants**

Serial No: Filed
10/600,251 06/23/2003
Title: Cranberry Amido Amines and Betaines as a Delivery
System for Natural
Antioxidants

Serial No: Filed:
10/620,899 07/17/2003
Title: Guerbet Cranberry Esters as a Delivery System for
Natural Antioxidants

4. All of these patents stand rejected under 35 USC 112 because it is claimed the "R" component is not properly defined as not to be clear to one of ordinary skill in the art.
5. In order to address this issue, it must be understood that natural oils are defined by several concepts.

a. The source of the oil

The four applications are very clear on this matter:

American cranberries, *Vaccinium macrocarpon*, are native plants of open, acid peat bogs in North America. Cranberry plants are evergreen perennial vines that produce runners and upright branches with terminal flower buds.

Raspberry Oil

The oil is referred to as *Rubus idaeus* seed oil and has a CAS number of 381718-28-

b. The process of extracting.

The applications clearly state the particular patent describing the cold pressed oil U.S. patent 6,391,345 issued May 2002 describes the refining of cold pressed oils and incorporate the patent by reference.

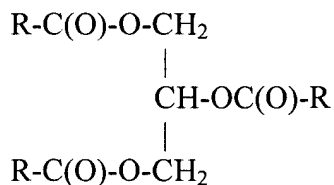
c. The composition of the oil

The oils processed by a particular process have salient properties. One is carbon distribution (typically C-16 to C-18 esters either saturated or mono or di unsaturated fatty acids); the other important aspect is the non-triglyceride active components present. The current applications not only distinctly claim the carbon distribution using names known to those skilled in the art. But also gives ranges of each component, than defines all these active components.

Applicants clearly state:

A. Raspberry

[015] Cold Pressed Raspberry Oil is a triglyceride conforming to the following structure:



[016] The oil is referred to as *Rubus idaeus* seed oil and has a CAS number of 381718-28-1

The R-C(O)- group has the following composition:

| <u>Component</u> | <u>% Weight</u> |
|------------------------|-----------------|
| 18:1 oleic | 10-20 |
| 18:2 linoleic | 30-40 |
| 18:3 linolenic (alpha) | 45-55 |
| alpha tocopherol | 46 mg/gram |
| Ellagic Acid | 450-650 ppm |

[017] Distribution by type of fatty group

| <u>Component</u> | <u>% Weight</u> |
|-------------------------|-----------------|
| Saturated | 3% |
| Polyunsaturated content | 86% |
| Mono unsaturated | 11% |

[018] The oil contains the following very critical “active” components for skin and hair care:

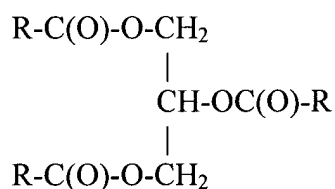
| <u>Material</u> | <u>Concentration</u> |
|------------------------|----------------------|
| 18:3 linolenic (alpha) | 45-55% |
| alpha tocopherol | 46 mg/gram |
| Ellagic Acid | 450-650 ppm |

Applicants then point out the unexpected benefit of the products derived from the oil:

[019] As can be seen, the cold pressed raspberry seed oil is a rich source of compounds having important properties when applied to hair and skin. The cold pressed raspberry oil can shield against UV-A induced damage by scattering light as well as by light spectrum absorption. The cold pressed raspberry oil has, then activity as a broad spectrum UV protectant. The raspberry oil may be used alone or in combination with other recognized conventional sunscreens. (emphasis Added)

B. Cranberry

[[015] Cold Pressed Cranberry Oil is a triglyceride conforming to the following structure:



[016] The R-C(O)- group has the following composition:

| Component | % Weight |
|---------------------------|------------|
| 16:0 palmitic | 5.0 to 6.0 |
| 18:0 stearic | 1.0 to 2.0 |
| 18:1 oleic | 20 to 25 |
| 18:2 linoleic | 35 to 40 |
| 18:3 linolenic (alpha) | 30 to 35 |
| 20:0 arachidic | 0.13 |
| 20:1 gadoleic | 0.20 |
| 20:5 (n-3) | 0.32 |
| 22:2 | 1.1 |
| Myristic | 0.01 |
| Pentadecanoic | 0.02 |
| Palmitoleic (trans) | 0.13 |
| Palmitoleic (cis) | 0.08 |
| 10-heptadecanoic | 0.03 |
| Gamma linolenic | 0.1 to 0.2 |
| Nonadecanoic | 0.1 to 0.2 |
| 11-transeicosenic | 0.22 |
| 11, 14 eicosandienoic | 0.1 |
| 11, 14, 17 eicosatrienoic | 0.01 |
| Eicosapentaenoic | 0.01 |
| Behenic | 0.03 |
| Erucic | 0.02 |
| Docosapentaenoic | 0.01 |
| Tricosanoic | 0.01 |
| Lignoceric | 0.02 |
| Nervonic | 0.02 |

[017] The oil also contains the following very critical “active” components for skin and hair care:

| Compound | mg/kg |
|------------------------------------|--------|
| Campesterol/brassicasterol (mg/kg) | 66.0 |
| Stigmasterol (mg/kg) | 68.0 |
| Beta-sitosterol (mg/kg) | 1319.0 |
| Phosphatidylinositol (mg/kg) | 9.9 |
| Phosphatidylcholine (mg/kg) | 202.0 |
| Alpha-tocopherol (mg/kg) | 341.0 |
| Gamma-tocopherol (mg/kg) | 110.0 |

[018] When the oil is exposed to conventional extraction procedures of steam stripping and solvent extraction, the concentration of the “active” components drops to vanishingly small levels and the activity is lost.

[019] As can be seen, the cold pressed cranberry seed oil is a rich source of compounds having important properties when applied to hair and skin. Stigmasterol is an anti-stiffness factor. Beta-sitosterol has use as an antihyperlipoproteinemic agent. One or more of the campesterol, stigmasterol and beta-sitosterol has inflammatory and may be useful in the treatment of gingivitis, rash, eczema, and other skin lesions. It is also believed that these compounds found in cranberry seed oil have activity as sunscreen agents, since some of the compounds present in cranberry oil have absorbance in the UV-B range. This is this range that causes the greatest cellular damage to humans. The cold pressed cranberry oil can shield against UV-A induced damage by scattering light as well as by light spectrum absorption. The cold pressed cranberry oil has, then activity as a

broad spectrum UV protectant. The cranberry oil may be used alone or in combination with other recognized conventional sunscreens.

6. The current applications then go on to claim:

R is derived from cold pressed cranberry or raspberry oil.

This term links all attributes of the oil together and specifies the oil from which they are derived. This is the best most effective way to specify all of the properties described above using the antecedent basis provided throughout the applications.

7. There is simply no better way known to this expert to get all of the elements as well defined as in the current application. I clearly know all attributes of the product claimed.

In conclusion, in my expert opinion, the Applicant language saying R is derived from cold pressed oil has proper antecedent basis and is abundantly clear to one of ordinary skill in the art.

Further declarant sayeth not.

Original Signed

David C. Steinberg
Declarant
April 16, 2006

(L) Related proceedings appendix page(s).

There are four appeals that relate to exactly the same issue. They are:

1) ZEN-012

In re Application of: O'Lenick

Examiner: Meller, Michael V.

Group Art Unit: 1655

Serial No: 10/444,471

Filed: 05/27/2003

Title: Guerbet Raspberry Esters as a Delivery System for Natural Antioxidants

2) ZEN-013

In re Application of: O'Lenick

Examiner: Meller, Michael V.

Group Art Unit: 1655

Serial No: 10/444,470

Filed: 05/27/2003

Title: Guerbet Cranberry Esters as a Delivery System for Natural Antioxidants

3) ZEN 15

In re Application of: O'Lenick

Examiner: Meller, Michael V.

Group Art Unit: 1655

Serial No: 10/600,251

Filed: 06/23/2003

Title: Cranberry Amido Amines and Betaines as a Delivery System for Natural Antioxidants

4) ZEN 017

In re Application of: O'Lenick

Examiner: Meller, Michael V.

Group Art Unit: 1655

Serial No: 10/620,899

Filed: 07/17/2003

Title: Cranberry Alkoxy Esters as a Delivery System for Natural Antioxidants